

**DRUG ACTIONABLE BECAUSE OF POTENTIAL DANGER WHEN USED
ACCORDING TO DIRECTIONS**

4121. Misbranding of Isopto Alkaline. U. S. v. 26 Cartoned Bottles * * *.
(F. D. C. No. 34907. Sample No. 67271-L.)

LABEL FILED: March 20, 1953, Eastern District of Louisiana.

ALLEGED SHIPMENT: On or about December 26, 1952, by Alcon Laboratories, Inc., from Fort Worth, Tex.

PRODUCT: 26 cartoned bottles of *Isopto Alkaline* at New Orleans, La. Examination showed that the product was contaminated with *Pseudomonas aeruginosa*.

LABEL, IN PART: (Bottle) "15 cc. Isopto Alkaline Alcon Brand Of Physiologic Methyl Cellulose Ophthalmic 1% with Benzalkonium Chloride 1:50,000 in saline solution **INDICATIONS:** As a vehicle for Ophthalmic drugs, which are stable in an alkaline (pH 7.4) menstruum. **Directions:** One to two drops in eye(s) three times daily, or as directed by Physician."

NATURE OF CHARGE: Misbranding, Section 502 (j), the article was dangerous to health when used in the dosage and with the frequency prescribed, recommended, and suggested in its labeling, namely, as a vehicle for ophthalmic drugs, used 3 times daily.

DISPOSITION: May 4, 1953. Default decree of condemnation and destruction.

VIOLATIVE SALES OF PRESCRIPTION DRUGS

4122. Misbranding of dextro-amphetamine sulfate tablets and secobarbital sodium capsules. U. S. v. Clyde King (Clyde King Drug Co.), and Benjamin H. Darnell. Pleas of guilty. Fine of \$50 against each defendant.
(F. D. C. No. 34841. Sample Nos. 46279-L to 46283-L, incl., 46285-L.)

INFORMATION FILED: May 13, 1953, Northern District of Alabama, against Clyde King, trading as the Clyde King Drug Co., Birmingham, Ala., and Benjamin H. Darnell, a pharmacist for the company.

NATURE OF CHARGE: On or about July 18, 21, 26, 28, and 29, 1952, while a number of *dextro-amphetamine sulfate tablets* and *secobarbital sodium capsules* were being held for sale at the Clyde King Drug Co., after shipment in interstate commerce, various quantities of these drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

Clyde King was charged as a defendant in each of the 6 counts of the information, and Benjamin H. Darnell was joined as a defendant in 3 of the counts.

DISPOSITION: May 25, 1953. The defendants having entered pleas of guilty, the court fined each defendant \$50.

4123. Misbranding of dextro-amphetamine sulfate tablets and methyltestosterone tablets. U. S. v. Holt Chapman (Chapman's Pharmacy). Plea of guilty. Fine of \$50. (F. D. C. No. 34872. Sample Nos. 2456-L, 2640-L, 2644-L, 2649-L, 2656-L.)

INFORMATION FILED: September 15, 1953, Middle District of Georgia, against Holt Chapman, trading as Chapman's Pharmacy, Macon, Ga.

NATURE OF CHARGE: On or about October 22, 27, and 31, and November 12, 1952, while a number of *dextro-amphetamine sulfate tablets* and *methyltestosterone*

tablets were being held for sale at Chapman's Pharmacy, after shipment in interstate commerce, the defendant caused a number of these tablets to be dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

DISPOSITION: September 29, 1953. The defendant having entered a plea of guilty, the court imposed a fine of \$50.

✓ **4124. Misbranding of Amytal Sodium capsules, dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, and methyltestosterone tablets.** U. S. v. Drive-In Drug Store, a partnership, and Dale E. Dunn and Ralph C. Dunn. Pleas of guilty. Fine of \$1,500 against partnership; sentence of 1 year in jail against each individual suspended. (F. D. C. No. 34864. Sample Nos. 13812-L, 14562-L, 14565-L, 14570-L, 14571-L, 14575-L.)

INFORMATION FILED: On or about May 21, 1953, District of Utah, against the Drive-In Drug Store, a partnership, Salt Lake City, Utah, and Dale E. Dunn, a partner in the partnership, and Ralph C. Dunn, an employee of the partnership.

NATURE OF CHARGE: On or about September 19 and 29 and October 5, 14, and 22, 1952, while a number of *Amytal Sodium capsules, dextro-amphetamine sulfate tablets, amphetamine sulfate tablets, and methyltestosterone tablets* were being held for sale at the Drive-In Drug Store, after shipment in interstate commerce, various quantities of these drugs were dispensed without a prescription from a practitioner licensed by law to administer such drugs. These acts of dispensing were contrary to the provisions of Section 503 (b) (1), and resulted in the dispensed drugs being misbranded while held for sale.

The partnership was charged in each of the six counts of the information with causing the dispensing of the drugs involved; Dale E. Dunn was joined as a defendant in count 4 relating to the dispensing of a quantity of *dextro-amphetamine sulfate tablets*, and Ralph C. Dunn was joined as a defendant in the other counts of the information.

DISPOSITION: Pleas of guilty having been entered, the court, on June 27, 1953, fined the partnership \$6,000 and sentenced each individual to 1 year in jail. On July 10, 1953, following a hearing on a motion for a reduction of the sentence, the court reduced the fine against the partnership to \$1,500 and suspended the jail sentence previously imposed against the individual defendants.

DRUGS ACTIONABLE BECAUSE OF FAILURE TO BEAR ADEQUATE DIRECTIONS OR WARNING STATEMENTS

4125. Misbranding of sulfoxazole tablets. U. S. v. Morris H. Bennett (Rex Drugs), and George C. Hoss. Plea of not guilty by Defendant Bennett and plea of guilty by Defendant Hoss. Tried to the court. Verdict of not guilty as to Defendant Bennett. Fine of \$50 against Defendant Hoss. (F. D. C. No. 33732. Sample No. 26256-L.)

INFORMATION FILED: November 13, 1952, Eastern District of Pennsylvania, against Morris H. Bennett, trading as Rex Drugs, Philadelphia, Pa., and George C. Hoss, an employee.

ALLEGED VIOLATION: On or about January 19, 1952, while a number of *sulfoxazole tablets* were being held for sale at Rex Drugs, after shipment in